AN ACT

ENTITLED, An Act to amend rule-making authority and rules to allow certain facilities and hospice programs to redispense certain pharmaceutical drugs under certain circumstances.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

Section 1. That § 36-11-11 be amended by adding thereto a NEW SUBDIVISION to read as follows:

Redispensing of pharmaceuticals.

Section 2. That ARSD 20:51:15:01 be amended by adding thereto a NEW SUBDIVISION to read as follows:

"Hospice program," a coordinated program of inpatient services providing palliative rather than curative care for a patient.

Section 3. That ARSD 20:51:13:02.01 be amended to read as follows:

20:51:13:02.01. Return of unused unit dose drugs by patients in hospice programs, nursing facilities, or assisted living facilities. Only unused unit dose drugs from patients in a hospice program, a nursing facility, or an assisted living facility may be returned to the pharmacy that dispensed the drugs for credit and redispensing if the following requirements are met:

(1) The facility or hospice program consults with a licensed pharmacist to oversee the drug distribution to ensure that a person trained and knowledgeable in the storage, use, and administration of the drug has been in control of any unit dose drug being returned to the pharmacy and that the unit dose drug has not come into the physical possession of the person for whom it was prescribed;

(2) The pharmacy's manager has received written approval from the board of a protocol detailing the procedure used to repackage, label, transfer, restock, redispense, and credit any unit dose drugs returned to the pharmacy;

(3) The drugs are provided in the manufacturer's unit dose packaging or are repackaged by the

pharmacy in a hermetically sealed single unit dose container that meets Class A or Class B standards on pages 1937 and 1938 of the United States Pharmacopeia;

(4) The unit dose package is labeled by the manufacturer with the drug lot number and expiration date;

(5) If the drug is repackaged by the pharmacy, each single unit dose prepackaged or repackaged container must be labeled in accordance with this regulation. Labeling must include the following:

(a) Name and strength of the medication;

(b) A suitable expiration date which shall not be later than the expiration date on the manufacturer's container, or one year maximum from the date the drug is prepackaged or repackaged;

(c) The date the product was prepackaged or repackaged;

(d) The manufacturer's lot number, expiration date, and identity;

(e) The identity of the pharmacist responsible for prepackaging or repackaging;

If the requirements of subdivisions (d) and (e) are maintained in the internal records of the drug outlet, those requirements may be omitted from the labeling.

(6) The drug's packaging is tamper resistant and shows no evidence of contamination, such as an opened or stained container;

(7) The unit dose drugs have not reached the expiration date;

(8) The drugs have not been dispensed in packaging that intermingles different drugs in a single compartment; and

(9) The drugs are not controlled drugs.

Unused unit dose drugs that are returned under this section may be redispensed pursuant to § 20:51:13:02.03.

Section 4. That ARSD 20:51:13:02.03 be amended to read as follows:

20:51:13:02.03. Redispensing unit dose drugs returned from hospice programs, nursing facilities, or assisted living facilities. Unused unit dose drugs that are returned under § 20:51:13:02.01 may be redispensed under the following conditions:

(1) Drugs may not be removed and repackaged from the returned unit dose package prior to redispensing;

(2) Drugs in a manufacturer's unit dose package may be redispensed as often as necessary, if the integrity of the original product and package is maintained;

(3) Drugs which have been repackaged into a unit dose package by the pharmacy may be redispensed into a unit dose distribution system and mixed with drugs of a different lot number provided that all lot numbers and expiration dates are placed on the unit dose package;

(4) Drugs may be removed from a unit dose package for dispensing in a traditional dispensing system as defined in § 20:51:21:01.

An Act to amend rule-making authority and rules to allow certain facilities and hospice programs to redispense certain pharmaceutical drugs under certain circumstances.

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I certify that the attached Act originated in the

HOUSE as Bill No. 1165

_____
Chief Clerk

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_____
Speaker of the House

Attest:

_____
Chief Clerk

_____
President of the Senate

Attest:

_____
Secretary of the Senate

House Bill No. 1165
File No. ____
Chapter No. _____

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Received at this Executive Office this _____ day of _____ ,

20____ at _____ M.

By _____
for the Governor

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The attached Act is hereby approved this _____ day of _____ , A.D., 20___

_____
Governor

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STATE OF SOUTH DAKOTA,
ss.
Office of the Secretary of State

Filed _____ , 20___
at _____ o'clock __ M.

_____
Secretary of State

By _____
Asst. Secretary of State